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EXHIBIT 1 PART 6

is considered to be that number of claims to which direct reference is made therein and must be considered in the same manner as a plurality of single dependent claims. See MPEP § 608.01(n), paragraph I. The same would be true for multiple dependent claims that are dependent on other multiple dependent claims.

multiple dependent claims.

Comment 205: One comment suggested that there should be a limit of twenty claims in every application with no exceptions and no requirement for an examination support document. Another comment suggested that the Office should limit the number of claims of any application to twenty or thirty total claims, and two or three independent claims. One comment suggested that there should simply be a hard cap without an option to file an examination support document to have additional claims examined. The comment argued that this would not take away any substantive rights, as long as applicant's right to file continuing applications and requests for continued examination is preserved.

Response: This final rule

appropriately balances applicants' interests to have an adequate number of claims to protect their inventions and the need to reduce the large and growing backlog of unexamined patent applications, improve the quality of issued patents, and make the patent examination process more effective. The changes to § 1.75 in this final rule permit an applicant to present five or fewer independent claims and twentyfive or fewer total claims in the application without submitting an examination support document in compliance with § 1.265. The changes to § 1.75 in this final rule also permit an applicant to present more than five independent claims or more than twenty-five total claims if the applicant files an examination support document in compliance with § 1.265.

Comment 206: Several comments suggested that the Office should adjust the fees if excess claims fees are insufficient to permit examination of the claims for which they are paid. One comment suggested that there should be higher fees for claims in excess of ten. Several comments suggested that there should be higher fees for claims in excess of twenty. One comment suggested higher fees for independent claims in excess of three. One comment suggested that there should be a higher fee for independent claims in excess of ten and total claims in excess of fifty. Several comments suggested that there should be escalating fees for increasing numbers of claims. One comment argued that applicants should be

permitted to designate a number of claims, without an examination support document, that varies with the filing fee paid. One comment suggested that applicants should be charged in proportion to the number of designated claims, and that, optionally, an upper bound on the number of claims (e.g., twenty-five total claims, no more than twelve independent claims) could be established.

Response: Excess claims fees are set by statute. See 35 U.S.C. 41(a). The Office sought a legislative change to increase excess claims fees, and while some increases were made in the Consolidated Appropriations Act, 2005, the Office did not obtain the increases that it considered necessary. In any event, the changes adopted in this final rule will help to focus examination and increase quality.

Comment 207: Several comments suggested that excessive claiming should be dealt with on a case-by-case basis, rather than by penalizing all applicants. One comment suggested that the Office should consider strategies under present § 1.105 to address problem applications on a case-by-case basis. A number of comments suggested that the requirement for an examination support document should be imposed on a case-by-case basis, only in those situations that impose a unique burden on the Office.

Response: As discussed previously, the Office is not adopting the "representative claims" examination approach under which the majority of applicants would have been required to either designate dependent claims for initial examination or file an examination support document. The changes adopted in this final rule require the applicant to file an examination support document under § 1.265 only if the applicant presents more than five independent claims or more than twenty-five total claims. If an examination support document in compliance with § 1.265 is not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims. The majority of applications do not contain more than five independent claims or more than twenty-five total claims. Therefore, as a result of the public comment, this final rule adopts an approach that avoids requiring a majority of applicants to make the choice between designating dependent claims for initial exâmination and filing an examination support document.

Comment 208: One comment suggested that one of the representative claims should be in Jepson format. Another comment suggested that fees should be increased on all non-Jepson claims. One comment suggested that the Office should charge less for claims written in Jepson format.

Response: There is no persuasive explanation as to why Jepson claims should be treated differently from non-Jepson claims. Furthermore, fees are set by statute and the statute does not provide the authority to charge higher or lower fees for Jepson claims.

lower fees for Jepson claims.

Comment 209: One comment suggested that there should be an expedited procedure for an application with a limit of five claims, a 1200-word specification, and four drawings, (with the filing fee being \$1000 for a small entity or \$3000 for a non-small entity), where the application could issue as a patent in fifteen months or less. One comment argued that the representative claim proposal should be an option for applicants and those applications with ten or fewer representative claims should be assigned a higher priority for examination. One comment argued that the examination support document should only be used as an optional procedure for an applicant to advance the application out of turn.

Response: The proposed "representative claims" examination approach is not adopted in this final rule. Further, the Office has revised its accelerated examination program with the goal of completing examination within twelve months of the filing date of the application. The application must contain three or fewer independent claims and twenty or fewer total claims, and the applicant must provide an accelerated examination support document and meet a number of other requirements. See Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination, 71 FR 36323 (June 26, 2006), 1308 Off. Gaz. Pat. Office 106 (July 18, 2006) (notice). However, requiring an examination support or similar document only as an optional procedure for applicant to advance the application out of turn would not result in the desired gains in efficiency and quality.

Comment 210: One comment suggested that if examination is limited to a certain number of claims, the Office should not be allowed to make a restriction requirement that is not linked to the burden of searching. Thus, the comment suggested that where different statutory classes or independent claims within a class do not really impose an additional burden,

they should not be counted against the examination limit.

Response: Under the current restriction practice, the burden of the search and examination in an application is considered before a requirement for restriction is made. See MPEP section 803. This includes where there are different statutory classes of invention or independent claims within a class that do not impose a search burden.

Comment 211: A number of comments argued that the one-month time period to reply to a notification of more than ten representative claims was too short to prepare and submit an adequate examination support document. One comment suggested that the time period should be at least two months with extensions of time being permitted. One comment suggested that the time period should be three months with extensions of time being permitted.

Response: The proposed "representative claims" examination approach is not adopted in this final rule. Under this final rule, applicant is required to provide an examination support document if applicant presents more than five independent claims or more than twenty-five total claims in an application. If an examination support document in compliance with § 1.265 is not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims. The time period provided in the notice requiring an examination support document is only applicable where it appears that the omission of an examination support document was inadvertent. Therefore, applicant should prepare and file an examination support document when applicant presents more than five independent claims or more than twenty-five total claims in an application. Applicant should not rely on the notification from the Office and a new period within which to prepare an examination support document. Nevertheless, the Office is revising this provision to provide a two-month time period that is not extendable under § 1.136(a), which should be sufficient for those situations in which an applicant inadvertently omitted an

examination support document.

Comment 212: A number of comments argued that the notice to the applicant under § 1.75(b)(3) would impose costs because it would have to be generated by an examiner and another round of communications would be needed if applicant suggests a restriction requirement and it is not accepted by the Office.

Response: Since the examination support document is required whenever applicant presents more than five independent claims or more than twenty-five total claims and the notice only applies when it appears that the omission of the examination support document was inadvertent, the Office expects that the number of notices would be relatively low. Furthermore, the Office plans to have a notice under § 1.75(b)(3) generated by someone other than the examiner. While it may be necessary on occasion for the examiner to communicate with the applicant if a suggested restriction requirement is not accepted, this additional communication is far outweighed by the benefits of focused examination and increased quality.

Comment 213: Several comments requested that the Office explain the procedures for how the Office will evaluate a suggested restriction requirement. Some comments questioned how an examiner will approve a suggested restriction requirement. One comment questioned what would occur if the restriction requirement was not accepted by the exâminer.

Response: As discussed previously, if the applicant submits a suggested restriction requirement, the suggested restriction requirement is accepted, and there are five or fewer independent claims and twenty-five or fewer total claims to the elected invention, the Office will simply treat the non-elected claims as withdrawn from consideration and proceed to act on the application (assuming the application is otherwise ready for action). The Office action will set out the requirement for restriction under § 1.142(a), e.g., in the manner that an Office action on the merits would contain a written record of a requirement for restriction previously made by telephone. See MPEP section

The refusal to accept a suggested requirement for restriction may result in the examiner making a different restriction requirement or making no restriction requirement. If the examiner makes a restriction requirement (different from the suggested restriction requirement), the applicant will be notified (a notice under § 1.75(b)(3) coupled with a restriction requirement) and given a time period within which the applicant must make an election. In addition, if there are more than five independent claims or more than twenty-five total claims to the elected invention and/or species, the applicant must also: (1) Amend the application

such that it contains no more than five independent claims and no more than twenty-five total claims to the elected invention and/or species; or (2) file an examination support document in compliance with § 1.265 that covers each claim (whether in independent or dependent form) to the elected

invention and/or species.

Comment 214: Several comments argued that the rules should provide guidance on how the non-extendable deadline would be treated in the event of a petition or appeal relating to the requirement for an examination support document. Several comments questioned how the notice and time period would be set when there are multiple applications that have patentably indistinct claims that are being considered together for purposes of determining the number of claims in an application.

Response: Applicant may file a petition under § 1.181 if the applicant disagrees with a determination that an application contains more than five independent claims or more than twenty-five total claims, or a determination that an examination support document does not comply with § 1.265. As stated in § 1.181(f), the mere filing of a petition will not stay any time period that may be running against the application. Applicant must file a reply in compliance with § 1.75(b)(3) within the two-month time period to avoid abandonment even when applicant files a petition under § 1.181. If there are multiple applications with at least one patentably indistinct claim, the Office will issue a notice under § 1.75(b)(3) in each application and set a separate time period in each application.

Comment 215: Several comments

argued that applicants would file more applications in parallel with fewer claims to avoid having to file an examination support document and this

would create more work for the Office.

Response: This final rule provides that if multiple applications contain at least one patentably indistinct claim, the Office will treat the multiple applications as a single application for purposes of determining whether each of the multiple applications exceeds the five independent claim and twenty-five total claim threshold. See § 1.75(b)(4). For example, if one of the claims in an application is patentably indistinct from at least one of the claims in another application, the Office will treat each application as containing the total of all of the claims in both applications when determining whether each application exceeds the five independent claim and twenty-five total claim threshold. This

provision is intended to prevent an applicant from submitting multiple applications to the same subject matter, each with five or fewer independent claims or twenty-five or fewer total claims, for the purposes of avoiding the requirement to submit an examination support document. Furthermore, under § 1.78(f), applicant is required to identify such applications if they: (1) Have filing dates that are the same as or within two months of each other, taking into account any filing date for which a benefit is sought under title 35, United States Code; (2) name at least one inventor in common; and (3) are owned by the same person, or subject to an obligation of assignment to the same person. If the applications also have the same claimed filing or priority date and substantially overlapping disclosures, applicant must rebut a presumption that the applications contain patentably indistinct claims or file a terminal disclaimer and provide good and sufficient reasons why two or more such pending applications are required rather than one. See §§ 1.78(f)(2) and (f)(3).

Comment 218: One comment questioned whether the Office would require an examination support document if a parent application issues as a patent with ten claims and a continuation application is filed with indistinct claims.

Response: The Office has revised § 1.75(b)(4) to provide that if there are multiple applications containing at least one patentably indistinct claim the Office will treat each of such applications as containing the total of all of the claims (both independent and dependent) present in all of the multiple applications containing patentably indistinct claims for purposes of determining whether each such application contains more than five independent claims or more than twenty-five total claims. Under § 1.75(b)(4), the Office will count the claims in copending applications containing patentably indistinct claims (including applications having a continuity relationship) but not in issued patents containing patentably indistinct claims, in determining whether each such application contains more than five independent claims or more than twenty-five total claims and thus whether an examination support document in compliance with § 1.265 is required. As discussed previously, this provision is to preclude an applicant from submitting multiple applications to the same subject matter (with claims that are patentably indistinct), each with five or fewer independent claims or twenty-five or fewer total claims, for the purposes of avoiding the requirement to

submit an examination support document in compliance with § 1.265. Although claims in an issued patent are not counted for the purposes of § 1.75(b)(4), the pending application may still be subject to a double patenting rejection.

Comment 217: One comment questioned how the Office would determine when an examination support document was "inadvertently" omitted

Response: If the omission of an examination support document is an isolated instance, then generally the omission would be considered inadvertent. Where, however, a particular individual (e.g., applicant or attorney) has a pattern of not including an examination support document when required, then the Office would be less inclined to consider such an omission as being inadvertent. The Office will not generally question whether the omission of an examination support document was inadvertent unless there is a reason to do so.

H. Examination Support Document Requirements

Comment 218: Several comments supported the concept of an examination support document. One comment agreed that the examination support document would help the Office to reduce the backlog.

Office to reduce the backlog.

Response: The Office is adopting the concept of an examination support document in this final rule. Under this final rule, an examination support document is required if applicant presents more than five independent claims or more than twenty-five total

claims in an application.

Comment 219: A number of comments argued that the search and analysis necessary to prepare an examination support document would add significant cost to the preparation of an application, that the cost would be significantly more than the \$2,500 predicted by the Office, and that this would significantly disadvantage independent inventors and small businesses. Several comments argued that it would be unaffordable for independent inventors and small entities. Several comments argued that the patentability search done by most practitioners is limited to United States patents and United States published applications and does not generally set forth in detail the patentability of each claim element by element. A number of comments argued that the examination support document was more like a validity search and opinion and included various estimates of the cost of preparing an examination support

document, which ranged from \$5,000 to \$30,000. One comment argued that it would cost a minimum of \$30,000 for a biotechnology application. One comment argued that even if the Office's estimate is accurate, it would cost a small entity applicant \$3,000 to have twenty claims examined, which would be a six hundred percent increase over current costs and would have a significant economic impact.

Response: As discussed previously, the Office has modified the proposed rules with respect to claims. Under the proposed rules, applicants who wished to have more than ten representative claims examined in the initial Office action would have had to file an examination support document. Under the changes in this final rule, applicants may have up to five independent and twenty-five total claims examined in an application without filing an examination support document.

The Office was given feedback that the costs for preparing an examination support document could be anywhere from \$5,000 to \$100,000. No data to support the alleged costs were submitted. Contrary to some of the comments, the Office is not requiring a validity search and opinion. The prefiling preparation of an application that contains more than five independent claims or more than twenty-five total claims should involve obtaining a patent novelty search, analysis and opinion. Preparation of an examination support document requires that this information be reduced to writing in a particular format.

The Office commissioned a detailed analysis of the final rule's impacts on small entities. This analysis indicated that the cost of an examination support document is likely to be in the range of \$2,563 to \$13,121. This analysis also concludes that this final rule is not expected to result in a significant economic impact on a substantial number of small entities. This final rule does provide an exemption from the requirement (§ 1.265(a)(3)) that an examination support document must, for each reference cited in the listing of the references required under § 1.265(a)(2), include an identification of all the limitations of each of the claims that are disclosed by the reference that applies to applications by a small entity as defined by the Regulatory Flexibility Act (5 U.S.C. 601

et seq.). See § 1.265(f).

Comment 220: Several comments argued that the examination support document is substantially more burdensome than the current procedure for accelerated examination because the search and examination support

document must separately address every claim for which examination is sought, and the rule contains substantial additional burdens. One comment argued that the accelerated examination procedure is too onerous as shown by the very small number of applicants who used the procedure, and the examination support document is even more stringent. Several comments argued that a petition to make special is voluntary, not mandatory. Furthermore, such a petition does not foreclose applicant's opportunity to pursue additional inventive subject matter to protect against design-arounds, as would happen in view of the concurrent

continuation proposed rule changes.

Response: The Office has reduced the requirements for an examination support document under § 1.265 as adopted in this final rule. The Office proposed to require applicants to provide a detailed explanation of how each independent and dependent claim was patentable over the cited art (proposed § 1.261(a)(4)). Section 1.265(a)(4) as adopted in this final rule requires applicants to provide the same explanation for the independent claims only. The Office also proposed to require applicants to provide statements of utility of the invention as defined in each independent claim (proposed § 1.261(a)(5)). Section 1.265 as adopted in this final rule does not include such a requirement. These changes reduce the requirements for applicants who wish to file an examination support document while still providing examiners with valuable information to assist in the examination of applications.

Furthermore, an examination support document in compliance with § 1.265 is required under § 1.75(b) only when an applicant presents more than five independent claims or more than twenty-five total claims. It is not required in applications that contain five or fewer independent claims and twenty-five or fewer total claims. Thus, the majority of applications would not need an examination support document since a majority of applications contain five or fewer independent claims and twenty-five or fewer total claims.
In addition, the accelerated

examination procedure was recently revised. The accelerated examination procedure has more requirements than are contained in § 1.265. See Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination, 71 FR at 36323-27, 1308 Off. Gaz. Pat. Office 106-09. For example, the accelerated examination support document must also identify any cited references that

may be disqualified as prior art under 35 U.S.C. 103(c) as amended by the Cooperative Research and Technology Enhancement (CREATE) Act (Pub. L. 108-43, 118 Stat. 3596 (2004))

Comment 221: Several comments argued that due to the cost and "duty to search," the requirement for an examination support document is tantamount to imposing a de facto limit on the number of claims in an

application.

Response: The Office has not placed a de facto limit on the number of claims. If an applicant wants to present more than five independent claims or more than twenty-five total claims, the applicant simply needs to submit an examination support document in compliance with § 1.265 before the first Office action on the merits. As discussed previously, the accelerated examination procedure has more requirements than are contained in § 1.265. However, over four hundred applications have been filed under the revised accelerated examination procedure in the last nine months.

Comment 222: One comment suggested that § 1.265 should be replaced by a requirement that applicant comply with the rules for a petition to make special. Another comment argued that applicants will file a petition to make special after going through the

effort and expense to prepare and file an examination support document.

Response: As discussed previously, the Office has recently revised its accelerated examination program with the goal of completing examination within twelve months of the filing date of the application. An application containing more than five independent claims or more than twenty-five total claims would not be eligible for the revised accelerated examination program. Nevertheless, the Office has no objection to every applicant filing his or her application under the revised accelerated examination program.

Comment 223: A number of comments argued that the requirement for an examination support document transfers to the applicant the costs and responsibilities of the examination process for which fees have been paid. One comment questioned why applicant must pay a search fee and perform a search of their own in order to prepare an examination support document. One comment suggested that the Office should consider eliminating the search and examination fee when an examination support document is provided. One comment argued that the excess claims fees that are paid are more than enough to cover the associated extra expense and burden placed on the

Office in examining the excess claims. One comment suggested that the excess claims fee should be increased rather than requiring applicants to submit an examination support document.

Response: Applications which contain a large number of claims absorb an inordinate amount of patent examining resources, and such applications are extremely difficult to process and examine properly. An applicant who presents more than five independent claims or more than twenty-five total claims will be required to assist the Office with the examination by providing an examination support document in compliance with § 1.265. The Office will still conduct a search and examine an application in which an examination support document is filed. Furthermore, the search and examination fees and excess claims fees do not recover the costs of searching and examining an application. The higher cost estimates provided in the comments on the Claims Proposed Rule confirm that the cost of conducting a search and preparing an analysis far exceeds the search and examination fees. The Office, however, cannot increase these fees because they are set by statute.

Comment 224: Several comments argued that the examination support document imposes extra burdens on the applicants that are not performed by the Office since applicants are required to translate any foreign documents not in the native language of the applicant and rejections by the Office do not comply with most of the requirements imposed under the rule.

Response: Examiners frequently obtain translations of foreign documents that they consider to be pertinent. Examiners must obtain a translation of any document that is in a language other than English if the examiner seeks to rely on that document in a rejection. See MPEP § 706.02. During examination, examiners cite references that are most closely related to the subject matter of the claims, identify the limitations of the claims that are disclosed by the references being relied upon in a rejection, explain how each of the independent claims are being rejected over the references being applied, and make determinations regarding utility and 35 U.S.C. 112, ¶ 1, support and enablement. The requirements in § 1.265 are intended to assist the examiner with the examination process.

Comment 225: Several comments stated that the costs and requirements of an examination support document would encourage applicants to seek the services of the least qualified searchers.

Response: The Office is not encouraging applicants to seek the services of the least qualified searchers. An applicant who decides to file an examination support document has the option to seek the services of any searcher he or she chooses or to conduct the preexamination search on his or her own. Applicant should have an incentive to hire the most qualified searchers since a better search is more likely to result in a more thorough examination. The requirements of an examination support document are clearly set forth in § 1.265 and an applicant who chooses to file an examination support document must satisfy these requirements. If the preexamination search is poor, then applicant runs the risk that the preexamination search or the examination support document will be deemed insufficient. If the preexamination search or examination support document is deemed insufficient, applicant will be given only a two-month time period that is not extendable under § 1.136(a) in which to file a corrected examination support document to avoid abandonment of the

application. See § 1.265(e).

Comment 226: One comment argued that the Office's estimate that the burden imposed by the rule change will equate to an additional one minute and forty-eight seconds to twelve hours was unrealistic for applications having multiple independent claims and hundreds of pieces of prior art to be reviewed.

Response: The one minute and fortyeight seconds to twelve hours response
time provided in the notice of proposed
rule making covered each activity that
may occur during the processing of an
application for patent (OMB control
number 0651–0031). The specific
estimate for an examination support
document was twelve hours (which has
subsequently been increased to twentyfour hours). While the Office received
comments suggesting that the Office's
cost estimate for an examination
support document was low, these
comments provided only conclusory
statements and contained few facts or
information.

Comment 227: A number of comments argued that it was almost impossible to determine the extent to which the prior art must be searched to satisfy the preexamination search requirement. Several comments argued that there is no way to meet the search requirements. One comment argued that it would be impossible to prove the "non-existence" of more pertinent art. A number of comments argued that the search should not be required to go

beyond the resources that are publicly available in the Office's search room. One comment suggested that the Office's search room would need to be upgraded to allow access to all foreign patents, periodicals and publications as well as all United States patents to meet the examination support document requirements. Several comments argued that applicant would be required to conduct a search that is beyond the scope of the searches performed by examiners and that this was unfair and burdensome to the applicants. Some comments argued that the information that must be identified is significantly more than what the Office provides to an applicant for a search and that a requirement for a statement that applicant has searched on the Office's database, the resources available to

examiners, should be sufficient.

Response: The standard for the preexamination search that is required is the same standard that the Office uses to examine patent applications, which is set forth in MPEP §§ 904–904.03. The information that applicant must identify is the same information that the examiner must record in the application file as set forth in MPEP § 719.05. If applicant follows the search guidelines set forth in the MPEP, then the preexamination search should be sufficient. The Office has published patent search templates to define the field of search, search tools, and search methodologies that should be considered when performing a search. The search templates are published on the Office's Internet Web site at http:// www.uspto.gov/web/patents/ searchtemplates/. The Office has requested comments on the patent search templates. See Request for Comments on Patents Search Templates, 71 FR 94 (May 16, 2006), 1307 Off. Gaz. Pat. Office 22 (Jun. 6, 2006).

The accelerated examination procedure has more requirements than are contained in § 1.265. See Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination, 71 FR 36232 (June 26, 2006), 1308 Off. Gaz. Pat. Office 106 (July 18, 2006) (notice). Thus, the information concerning the requirements for a preexamination search document under the revised accelerated examination procedure can be applied to fulfill the requirements for a preexamination search under § 1.265. See samples of a preexamination search document and an accelerated examination support document on the Office's Internet Web site at http:// www.uspto.gov/web/patents/ accelerated/.

Finally, a statement that applicant has searched on the Office's database and the resources available to examiners would not be sufficient. A mere statement that the applicant has searched on the Office's database and the resources available to examiners would not identify the field of search, the date of the search, and, for database searches, the search logic or chemical structure or sequence used as a query, the name of the file or files searched and the database service, and the date of the search. See § 1.265(a)(1).

Comment 228: One comment argued that the fact that foreign search reports are not sufficient for the preexamination search or examination support document seemed at odds with the objective of promoting greater reliance on and use of work done by other competent patent offices. One comment questioned whether an international search report is sufficient to satisfy the search requirement, and if it is, then why are foreign patent office searches not sufficient.

Response: Neither foreign search reports nor international search reports are per se excluded. If a foreign search report or an international search report satisfies the requirements for a preexamination search set forth in § 1.265, then it would be accepted.

Comment 229: One comment argued that the preexamination search requirement that the search must cover all the features of the designated dependent claims separately from the claim or claims from which the dependent claim depends makes no sense. The comment argued that if a dependent claim adds an element to the combination in an independent claim, a search for prior art references that disclose the additional element separately from the elements of the independent claim is likely to produce many references that have no relation to the invention. The comment suggested that the language of the rule be revised to clarify that the preexamination search must include a separate search for each independent claim and each designated dependent claim.

Response: As discussed previously, the Office did not adopt the "representative claims" examination approach. Under this final rule, if the application contains more than five independent claims or more than twenty-five total claims, applicant is required to file an examination support document in compliance with § 1.265 that covers each of the claims (whether in independent or dependent form) before the first Office action on the merits. If an examination support document in compliance with § 1.265 is

not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims. The Office has revised § 1.265(b) to delete the phrase "separately from the claim or claims from which the dependent claim depends." Section 1.265(b) as adopted in this final rule requires that the preexamination search must encompass all of the features of the claims (whether independent or dependent), giving the claims the broadest reasonable interpretation. For example, if independent claim 1 recites elements ABC and dependent claim 2 depends on claim 1, incorporates all the limitations of claim 1 and additionally recites element D, then, even if applicant cannot find elements ABC and believes elements ABC to be novel, applicant must still search for element D.

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Comment 230: One comment argued that the requirement that the search encompass the "disclosed features that may be claimed" should be deleted because it gives examiners carte blanche to reject preexamination searches on

essentially arbitrary grounds.

Response: The Office notes the concerns expressed in the public comment. The Office has modified the proposed provision such that § 1.265(b) as adopted in this final rule does not require that the preexamination search must encompass the disclosed features that may be claimed. For any amendment to the claims that is not encompassed by the examination support document, however, applicants are required to provide a supplemental examination support document that encompasses the amended or new claims at the time of filing the amendment.

Comment 231: Several comments suggested that there should be an exemption from the limits on the number of claims for independent inventors. One comment argued that many individual inventors lack the skills and requisite knowledge to perform an adequate preexamination search and prepare an examination

support document.

Response: The applicant of a patent application should have sufficient knowledge of his or her own invention. Performing a preexamination search and preparing an examination support document should be no more difficult than preparing and prosecuting the patent application. Furthermore, applicants can avoid the need to file an examination support document by not presenting more than five independent claims or more than twenty-five total

claims in an application. This final rule, however, provides that a small entity as defined by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) may claim an exemption from the requirement in § 1.265(a)(3) for an identification of all of the limitations of each of the claims that are disclosed by the references cited in the listing of the references required under § 1.265(a)(2). See § 1.265(f). Comment 232: One comment

suggested that the Office should hire experienced searchers to perform the

searching function.

Response: The Office has recently conducted a pilot using PCT international applications for competitively sourcing search functions to commercial entities, each of which had experience in providing patent searches. The purpose of the pilot program was to demonstrate whether searches conducted by commercial entities could meet or exceed the standards of searches conducted and used by the Office during the patent examination process. The pilot was not proved successful and was concluded after six months.

Comment 233: A number of comments argued that the rules requiring an examination support document are fraught with dangers in the form of inequitable conduct allegations and malpractice. One comment argued that there would be challenges on the sufficiency of the examination support document, the scope of the search of the examination support document, and the timing of the search for the examination support document. A number of comments argued that even a good faith attempt is likely to be attacked on the grounds of inequitable conduct, and that such a duty is contrary to Frazier v. Roessel Cine Photo Tech., Inc., 417 F.3d 1230, 75 U.S.P.Q.2d 1822 (Fed. Cir. 2005). A number of comments argued that the risk of inequitable conduct allegations in litigation would effectively force applicants to file ten or fewer claims, which would deny them the right to adequately protect their inventions. Several comments argued that each patent that includes an examination support document in its file history would be inherently weak given current inequitable conduct practices. Several comments argued that the likelihood of having to defend against inequitable conduct would reduce perceived public confidence in the validity of issued patents. Several comments also argued the examination support document will increase litigation costs. Several comments also argued that the added costs in terms of the perceived reduction in patent quality and the

potential litigation costs would outweigh any potential speed of examination benefit. One comment argued that forcing applicant's representatives to limit the claims to an arbitrary number is akin to asking them to commit what amounts to malpractice. One comment stated that the rules put applicants in a triple-jeopardy situation for losing patent rights. First, because examiners will not consider all initially filed claims, applicants are put in jeopardy of having to file continuations for unexamined claims. Second, if applicants choose to have more than the threshold number of claims, applicants risk inequitable conduct charges. Third, if only the threshold number of claims is pursued, applicants will be unable to

adequately protect their inventions.

Response: Applicants may present as many claims as they feel are necessary to adequately protect their invention. Under this final rule, applicant may present up to five independent claims and twenty-five total claims for examination in an application without providing an examination support document. As discussed previously, the Office has also modified the proposed changes to continuing application practice and continued examination practice to permit an applicant to file two continuation or continuation-inpart applications plus one request for continued examination in an application family, without any justification. Thus, an applicant is permitted to present up to fifteen independent claims and seventy-five total claims for each patentably distinct invention via an initial application and two continuation or continuation-inpart applications that are prosecuted serially without providing either an examination support document or a justification. Applicant may also present additional claims by submitting an examination support document under § 1.265 before the first Office action on the merits.

The changes in this final rule do not force an applicant to carry any affirmative duty that may expose him or her to a greater risk of inequitable conduct. The submission of an examination support document to assist the Office in gathering information for use during examination does not expose an applicant to a greater risk of inequitable conduct. Inequitable conduct is a doctrine based, in part, upon "intent to deceive." See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178, 33 U.S.P.Q.2d 1823, 1826 (Fed. Cir 1995). To establish inequitable conduct, a party must provide clear and convincing evidence of: (1) Affirmative misrepresentations of a material fact,

failure to disclose material information, or submission of false material information; and (2) an intent to deceive. See, e.g., Impax Labs., Inc. v. Aventis Pharm. Inc., 468 F.3d 1366, 1374, 81 U.S.P.Q.2d 1001, 1006 (Fed. Cir. 2006) (citing Alza Corp. v. Mylan Labs., Inc., 391 F.3d 1365, 1373, 73 U.S.P.Q.2d 1161, 1167 (Fed. Cir. 2004)). Absent such "intent to deceive" inequitable conduct cannot be proven. Unless the applicant has an "intent to deceive" when submitting an examination support document, the simple submission of an examination support document, even one containing erroneous information, to the Office does not by itself raise an intent to deceive or mislead the Office. See Frazier, 417 F.3d at 1236 n.1, 75 U.S.P.Q.2d at 1826 n.1 (the mere submission of erroneous information to the Office does not by itself raise an inference of intent to deceive or mislead). Moreover, frivolous allegations in litigation are subject to professional responsibility rules and Rule 11 of the Federal Rules of Civil Procedure.

Comment 234: A number of comments argued that the Office must create a "safe harbor" that appropriately protects the applicant from inequitable conduct allegations when identifying and characterizing important prior art. Several comments argued that changes to § 1.56 would need to be made to exempt examination support documents from it. One comment argued that legislative reform is needed. Several comments argued that implementation of the examination support document should be delayed until changes to inequitable conduct are made. A number of comments suggested that more meaningful participation by applicants in prosecution of the application requires adequate "safeharbor" provisions from inequitable conduct.

Response: The Office proposed revising § 1.56 to provide a "safe harbor" to applicants who make a reasonable good faith effort to comply with the proposed requirements. See Changes To Information Disclosure Statement Requirements and Other Related Matters, 71 FR at 38811–12, 38820, 1309 Off. Gaz. Pat. Office at 27, 34. Most of the comments indicated that such a "safe harbor" at best sets out the current state of the law of inequitable conduct, in that a "safe harbor" is unnecessary for applicants who act in good faith (i.e., without an intent to deceive or mislead the Office) because an intent to deceive or mislead the Office is a separate and essential component of inequitable conduct. See

e.g., Weatherchem Corp. v. J.L. Clark, Inc., 163 F.3d 1326, 1336, 49 U.S.P.Q.2d 1001, 1009 (Fed. Cir. 1998) (a finding that the patentee acted without any intent to deceive disposes of the inequitable conduct issue), and Manville Sales Corp. v. Paramount Systems Inc., 917 F.2d 544, 552, 16 U.S.P.Q.2d 1587, 1593 (Fed. Cir. 1990) (materiality does not presume intent, which is a separate and essential component of inequitable conduct). The comments also expressed concern that any "safe harbor" would possibly create new requirements with respect to an applicant's duty of disclosure under § 1.56. It is the Office's position that an applicant's duty of disclosure under § 1.56 with respect to an examination support document under § 1.265 is satisfied if an individual as defined in § 1.56(c) acted in good faith to comply with the requirements in § 1.265 for an examination support document. The Office, however, is not adopting changes to § 1.56 in this final rule to provide a "safe harbor" to applicants because such a provision would be unnecessary. The Office notes that patent reform legislation is pending in the 110th Congress before both the Senate and House of Representatives. See Patent Reform Act of 2007, S. 1145, 110th Cong. (2007), and H.R. 1908, 110th Cong. (2007). The Department of Commerce submitted a letter on May 18, 2007, to the Chairman of the House Subcommittee on Courts, the Internet. and Intellectual Property recommending that H.R. 1908 be amended to address the doctrine of inequitable conduct and unenforceability to ensure that patent applicants are not discouraged from fully and fairly sharing relevant information with the Office.

Comment 235: A number of comments argued that the examination support document would require the applicant to make binding admissions as to the scope of the claims and how they relate to the prior art references and thus force applicant to create prosecution history estoppel and address rejections that would never have occurred during prosecution. Several comments argued that such a requirement shows a complete lack of understanding of the pitfalls that admissions can have in litigation. Several comments argued that such statements can be misinterpreted and distorted in unforeseen ways. One comment argued that this may cause the practitioner to unintentionally and unnecessarily narrow the claims through the effect of prosecution history estoppel, which will decrease the commercial value and the quality of the

patent. Several comments argued that the requirement for an examination support document places applicant in a precarious position of having to provide as much information as possible to support patentability of the claimed invention while avoiding statements that can be easily manipulated in litigation. One comment argued that applicants would be put in a position of having to make statements against interest long before the scope of their invention is realized. One comment argued that requiring applicant to examine his or her own application creates a conflict of interest, which would raise a question of concealment or understatement.

Response: The best way to avoid prosecution history estoppel is by knowing what the prior art is and filing claims that initially define patentable subject matter without having to file an amendment. Conducting a preexamination search and preparing an examination support document will help applicants to draft a better written disclosure and more focused claims, thereby minimizing any prosecution history estoppel

history estoppel.

Comment 236: Several comments argued that the one-month non-extendable time period to respond to a notice requiring a corrected or supplemental examination support document is insufficient. Some comments suggested that a three-month time period, which is extendable up to six months with an extension of time, should be given. Some comments suggested that the time period should be at least three months or extensions of time should be permitted.

Response: The Office notes the concerns expressed in the public comment regarding the time period set forth in a notice requiring a corrected or supplemental examination support document when an examination support document is deemed to be insufficient The Office has revised the proposed provision such that § 1.265(e) provides a two-month time period that is not extendable under § 1.136(a). The twomonth time period should be more than sufficient to correct any minor deficiencies. Applicants, however, should not rely on the two-month time period in § 1.265(e) to prepare an examination support document or a supplemental examination support document. The requirements for an examination support document are clearly set forth in § 1.265. Applicant should prepare the examination support document in compliance with the requirements before presenting more than five independent claims or more than twenty-five total claims. Applicant

should also conduct the preexamination search to encompass all of the disclosed features that applicant expects to claim in order to avoid the need to update the preexamination search. Applicant should file a supplemental examination support document at the time applicant presents any amendment to the claims that is not covered by the previous examination support document. Applicant also has the option of canceling the requisite number of claims (independent or total) that necessitate an examination support document, rather than submitting a corrected or supplemental examination support document. Furthermore, extensions of this two-month time period in § 1.265(e) are available to those for which there is sufficient cause (§ 1.136(b)).

Comment 237: One comment suggested that if applicant's examination support document is deemed insufficient, applicant should be afforded an opportunity to undesignate claims, and if applicant fails to undesignate the claims or file a corrected examination support document, then the examiner should undesignate claims and proceed with examination, rather than holding the application abandoned.

Response: The Office is not adopting the "representative claims" examination approach in this final rule. Thus designation (or "undesignation") of dependent claims for initial examination is not required in this final rule. Under this final rule, if applicant wants to present more than five independent claims or more than twenty-five total claims in an application, applicant simply needs to submit an examination support document in compliance with § 1.265 before the first Office action on the merits. If applicant files an examination support document and it is insufficient. the Office will notify the applicant and give the applicant the options of either: (1) Filing a corrected or supplemental examination support document in compliance with § 1.265 that covers each of the claims (whether in independent or dependent form); or (2) amending the application such that it contains no more than five independent claims and no more than twenty-five total claims.

Comment 238: One comment argued that applicant should be given the options available under § 1.75(b)(3) and not be limited to submission of a corrected or supplemental examination support document when an examination support document is deemed to be insufficient or in other situations under § 1.265(e) (§ 1.261(c) as proposed).

Response: The Office notes the concerns expressed in the public comment regarding the proposed provision that requires a corrected or supplemental examination support document when an examination support document is deemed insufficient. The Office has modified this proposed provision such that § 1.265(e) provides that if an examination support document is insufficient, the Office will notify the applicant and give the applicant the options of either: (1) Filing a corrected or supplemental examination support document in compliance with § 1.265 that covers each of the claims (whether in independent or dependent form); or (2) amending the application such that it contains no more than five independent claims and no more than twenty-five total claims. However, applicants will not be given the option to submit a suggested requirement for restriction. Such an option would not be appropriate after applicant has already submitted an examination support document.

Comment 239: A number of comments requested clarification on how the Office would use an examination support document. Some comments questioned whether an independent search would be conducted and whether the cited references would be independently evaluated by the examiner. One comment noted that if the examiner simply adopts the results of the search and the conclusions of patentability, there would be a wide variation in quality and thoroughness of the searches performed, and in the quality of analysis of the search results. The comment further argued that if the examiner will perform further searching, then it was difficult to understand how the objective of "sharing the burden" is accomplished, since it would not seem to yield time or cost savings for the Office. Several comments argued that examiners should not give any faith and credit to the information in an examination support document. One comment argued that if the examiner does rely on the external search, the uncertainty of the patent will be increased. Another comment argued that the submission of an examination support document may motivate examiners to skip doing a thorough search, thus leading to lower patent quality. One comment argued that requiring an examination support document was a punitive measure because: (1) The examination support document requires information that is rarely if ever required, such as details

regarding literal support for the claim elements; (2) the Office does not indicate that examiners will receive additional time to review the examination support document; and (3) the Office has not indicated that it will rely on the external search.

rely on the external search.

Response: Upon taking up an application for examination, the examiner will consider the prior art submitted in an information disclosure statement in compliance with §§ 1.97 and 1.98 (see § 1.97(b)) and those filed with an examination support document in compliance with § 1.265 (required under § 1.75(b)), and make a thorough investigation of the available prior art related to the subject matter of the claimed invention (see $\S 1.104(a)(1)$). The examiner will make an independent patentability determination in view of the prior art on the record, other information in the examination support document, and any other relevant prior art or evidence. The examination support document will assist the examiner in the examination proces and the determination of patentability of the claims by providing the most relevant prior art and other useful information. It will help the examiner in understanding the invention and to focus on the relevant issues. The examination support document will also assist the examiner in evaluating the prior art cited by the applicant and in determining whether a claim limitation has support in the original disclosure and in any prior-filed application. The requirement for an examination support document is not a punitive measure, nor is it a substitute for the Office's examination. The information required in an examination support document is to assist the examiner with the more extensive examination of an application having more than five independent claims or more than twenty-five total claims.

The Office has reduced the requirements for an examination support document under § 1.265 as adopted in this final rule. The Office proposed to require applicants to provide a detailed explanation of how each independent and dependent claim was patentable over the cited art (proposed § 1.261(a)(4)). Section 1.265(a)(4) as adopted in this final rule requires applicants to provide the same explanation for the independent claims only. The Office also proposed to require applicants to provide statements of utility of the invention as defined in each independent claim (proposed § 1.261(a)(5)). Section 1.265 as adopted in this final rule does not include such a requirement. These changes reduce the requirements for applicants who

wish to file an examination support document while still providing examiners with valuable information to assist in the examination of

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applications.
Comment 240: Several comments questioned how the Office would determine if an examination support document is insufficient. Some comments also questioned what would happen if the Office knows of closer prior art than that cited by applicant. One comment questioned whether the examiner could hold the examination support document non-compliant if the examiner objects to the search or the claim scope and also what would be applicant's remedy. Several comments argued that applicants currently disregard §§ 1.56, 1.97 and 1.98 and fail to cite their own work. The comments argued that applicant will cite generic references to comply with § 1.265 and will likely not reveal the most pertinent art. One comment argued that the examination support document requirements are subjective. One comment suggested that the Office should institute a petition process for disputing the requirement for an examination support document or the holding that an examination support document is insufficient. The comment suggested that the requirement should be stayed pending the outcome of the petition, or applicants should at least be given sufficient time for the petition to be heard.

Response: The Office will review an examination support document to determine if it meets all the requirements set forth in § 1.265. As discussed previously, the accelerated examination procedure has more requirements than are contained in § 1.265. The Office has provided guidelines for examination support documents filed under the accelerated examination procedure. The Office's guidelines concerning the accelerated examination support document may be helpful to applicants who are preparing an examination support document under § 1.265. The guidelines under the accelerated examination procedure, search templates, and samples of a preexamination search document and an examination support document are available on the Office's Internet Web site at http://www.uspto.gov/web/ patents/accelerated/. The Office will provide similar guidelines for examination support documents under § 1.265, including the preexamination search statement, and will post such guidelines on the Office's Internet Web site. These guidelines should minimize subjectivity in evaluating whether an examination support document

complies with the requirements of

Section 1.265(a)(2) requires a listing of references deemed most closely related to the subject matter of each of the claims (whether in independent or dependent form). As discussed previously, the references that would be most closely related to the subject matter of each of the claims include: (1) A reference that discloses the greatest number of limitations in an independent claim; (2) a reference that discloses a limitation of an independent claim that is not shown in any other reference in the listing of references required under § 1.265(a)(2); and (3) a reference that discloses a limitation of a dependent claim that is not shown in any other reference in the listing of references required under § 1.265(a)(2). References that are only relevant to the general subject matter of the claims would not be most closely related as long as there are other references that are more closely related to the subject matter of the claims. Applicant may not exclude a reference from an examination support document simply because the reference was not the result of the preexamination search provided for in § 1.265(a)(1). References, from whatever source, that have been brought to the applicant's attention must be considered in determining the references most closely related to the subject matter of each of the claims. Accordingly, if applicant merely cites generic references and does not cite the most pertinent art (including applicant's own work), then the examination support document would most likely not be compliant with § 1.265. Simply because the Office knows of a closer prior art reference (that is not applicant's own work) than the prior art cited by the applicant is generally not enough to hold a preexamination search insufficient.

An examination support document could be deemed insufficient based on an insufficient search. If the preexamination search or examination support document is deemed insufficient, applicant will be given only a two-month time period that is not extendable under § 1.136(a) in which to file a corrected examination support document or amend the application to contain five or fewer independent claims and twenty-five or fewer total claims to avoid abandonment of the application. See § 1.265(e). Any applicant who disagrees with a requirement for an examination support document or the holding that an examination support document or preexamination search is insufficient may file a petition under § 1.181. As

provided in § 1.181(f), the mere filing of a petition will not stay any period for reply that may be running against the application. The Office will make every effort to decide petitions in a timely manner.

Comment 241: A number of comments argued that it was unfair and inconsistent for the Office to require applicants to produce an examination support document when the Office is not effectively using foreign search reports. One comment argued that since the Office is unwilling to accept a foreign search report or use international search reports prepared by the Office itself, the examination support document would not reduce pendency. Another comment argued that since examiners ignore international search reports they would not consider an examination support document.

Response: The Office will consider any prior art submitted by applicant in an examination support document in compliance with § 1.265 (required under § 1.75(b)) and an information disclosure statement in compliance with §§ 1.97 and 1.98 including those that are filed with a foreign search report or an international search report. Any relevant prior art will assist the examiner in the determination of patentability of the claims. The examiner, however, must make an independent determination of patentability of the claims in the application. The examiner cannot accept the determination of patentability by another examiner in a foreign application or an international application because the patentability standard of a foreign or international application is different than the

standard in a U.S. application.

Comment 242: A number of comments argued that the requirement for an examination support document would create more work for the examiner since the examiner would have to determine the adequacy of the examination support document. One comment argued that complex cases would continue to be complex and the Office would just have the additional tasks of determining whether or not an examination support document should be required, and whether or not an examination support document is sufficient. One comment argued that examiners will not have sufficient time to review the examination support documents and that examiners would need more time for reviewing the examination support documents. The comment questioned whether this would take the place of the examiner reviewing the specification. Several

comments argued that determining the adequacy of examination support documents would divert resources from examination and prolong pendency. One comment argued that there would be additional burdens on the examiner in having to impose the requirement for designation of claims, issue communications challenging the sufficiency of the examination support document, perform a different search after claims are amended in response to an Office action, and search and examine the non-designated claims after allowance of designated claims. One comment argued that the number of petitions would increase because of petitions regarding whether an examination support document was needed or defective.

Response: Under this final rule, applicant is required to file an examination support document under § 1.75(b)(1) if applicant presents more than five independent claims or more than twenty-five total claims in an application. If an examination support document in compliance with § 1.265 is not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims. The majority of the applicants would not need to file an examination support document. The requirements of an examination support document are clearly set forth in § 1.265. Applicants should comply with the requirements at the time applicant presents more than five independent claims or more than twenty-five total claims in an application. As discussed previously, any relevant prior art and other information provided in an examination support document will assist the examiner in the examination process and in the determination of patentability of the claims. During the examination process, the examiner will consider all relevant prior art and information, and interpret the claims in light of the specification. The examiner will review the specification even when applicant files an examination support document. Thus, the benefits obtained by the examination support document would outweigh the Office's additional task of determining whether or not it is sufficient or is required.

Comment 243: One comment questioned whether the Office would give examiners less time to examine those applications in which an examination support document is filed and, if not, then how would the workload be reduced.

Response: Changes to patent examiner production goals are beyond the scope of the proposed changes to the rules of practice. Therefore, whether examiners should be given less time to examine certain applications is not discussed in this final rule. The Office expects that these rule changes will result in a more focused quality examination. The information provided in the examination support document will assist the examiner with the more extensive examination of the application. This information will be available to the examiner up front and will include the most closely related references and a detailed explanation of how the claims are patentable over these references. As a result, the exchanges between examiners and applicants should be more efficient and effective, the number of Office actions should be reduced, prosecution should be concluded faster, and the need to file a continuation application or request for continued examination should be reduced. Thus, the Office's workload would be reduced.

Comment 244: Several comments argued that the requirement for the broadest reasonable interpretation of the claims in conducting the search for an examination support document is inconsistent with current case law citing In re Johnston and In re Donaldson that require the Office to interpret the claims reasonably in light of the specification.

Response: The requirement in 1.265(b) is consistent with current case law. The current case law requires that during examination the claims must be given their broadest reasonable interpretation consistent with the specification. According to case law, however, the broadest "reasonable" interpretation is necessarily one that is consistent with the specification. See, e.g., Phillips, 415 F.3d at 1316, 75 U.S.P.Q.2d at 1329; In re Morris, 127 F.3d 1048, 1054, 44 U.S.P.Q.2d 1023, 1027 (Fed. Cir. 1997) ("Some cases state the standard as the broadest reasonable interpretation, others include the qualifier consistent with the specification or similar language. Since it would be unreasonable for the PTO to ignore any interpretive guidance afforded by the applicant's written description, either phrasing connotes the same notion: As an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's

specification.") (citations omitted). Therefore, the reference in § 1.265(b) to giving the claims "the broadest reasonable interpretation" is consistent with case law.

Comment 245: One comment agreed that the requirements relating to the concise statement of utility and the 35 U.S.C. 112 showing is sharing the burden of examining all of the claims in the application, but argued that requiring applicant to characterize the prior art goes too far and is best left to the examiner since it is the examiner's role to review and analyze the prior art for patentability purposes in view of § 1.104. Several comments argued that the burden of the examination belongs with the Office and that it is against the public interest to shift the burden from the examiner to the applicant. One comment argued that the examination support document requirement asks applicant to prove that patent claims are patentable, which is essentially impossible. One comment argued that the only purpose of an examination support document is to force applicants to do what they already should be doing, that is, carefully comparing their claims to every close prior art reference and adding limitations to distinguish the claims.

Response: Ultimately it is the Office's responsibility to determine patentability. Nevertheless, it is appropriate for applicants to provide information regarding an initial review of claims to assist the Office in determining patentability in applications where they feel they need to have more than five independent claims or more than twenty-five total claims. There is no reasonable explanation as to why it is against public interest for an applicant who presents more than five independent claims or more than twenty-five total claims to provide additional information to the Office. The Office is not requiring applicants to prove that their claims are patentable. The Office is simply requiring applicants who present more than five independent claims or more than twenty-five total claims to provide additional information to the Office by conducting a preexamination search and submitting an examination support document. The Office agrees that applicants should be comparing their claims to every close prior art reference and adding limitations to distinguish the claims.

Comment 246: One comment stated the Office should require a showing of precise written description (35 U.S.C. 112, ¶ 1) support for all amendments made by applicants.

Response: Applicant should specifically point out the support for any amendments made to the disclosure. See e.g., MPEP § 2163.06. Furthermore, when applicant adds a new claim limitation in an application that contains more than five independent claims or more than twenty-five total claims, applicant is required to submit a supplemental examination support document that includes a showing of where such new claim limitation finds support under 35 U.S.C. 112, ¶ 1, in the wriften description of the specification and in any parent application. In addition, the examiner may require the applicant to show where the specification of the application or a parent application provides written description support under 35 U.S.C. 112, ¶ 1, for a new limitation. See § 1.105(a)(1)(ix) (as adopted in this final rule).

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Comment 247: One comment argued that the concise statement of utility and the 35 U.S.C. 112 showing required in an examination support document make no sense. The comment argued that cross-referencing each line of the claims back to the specification is a waste of time. One comment argued that applicants should not have to admit what is disclosed, but rather they should only have to admit what is not

Response: In view of the comments, the Office is not adopting the requirement that an examination support document contain a concise statement of the utility of the invention as defined in each of the independent claims. The showing of where each limitation of the claims finds support under 35 U.S.C. 112, ¶ 1, however, would be helpful to the examiner. The examiner is responsible for determining whether or not there is 35 U.S.C. 112, ¶ 1, support in the written description for claimed subject matter. If applicant provides this information, it will assist the examiner in the examination of the application by making it easier for the examiner to make the necessary determinations. See Hyatt v. Dudas, 2007 U.S. App. LEXIS 15350 (Fed. Cir. Jun. 28, 2007). The applicant should be aware of where each limitation of the claims finds support under 35 U.S.C. 112, ¶ 1, in the written description by virtue of having prepared the application. There is no justification for requiring the examiner to duplicate this effort in an application that exceeds the five independent claim and twenty-five total claim threshold set forth in § 1.75(b).

Comment 248: One comment argued that § 1.265(a)(2) through (a)(4) resurrects provisions that used to be in the rules, but were amended out of the rules in 1992 when they were found to be unworkable.

Response: The Office proposed a number of changes to the rules of practice around 1990 related to the duty of disclosure and the filing of information disclosure statements. See Duty of Disclosure, 56 FR 37321 (Aug. (Aug. 27, 1991) (proposed rule), and Duty of Disclosure and Practitioner Misconduct, 54 FR 11334 (Mar. 17. 1989), 1101 Off. Gaz. Pat. Office 12 (Apr. 4, 1989) (proposed rule). The Office ultimately adopted changes to the duty of disclosure provisions of § 1.56 and the information disclosure statement provisions of §§ 1.97 and 1.98 (and deleted § 1.99) in 1992. See Duty of Disclosure, 57 FR 2021 (Jan. 17, 1992), 1135 Off. Gaz. Pat. Office 13 (Feb. 13, 1992) (final rule). The changes adopted in the 1992 final rule concerning the duty of disclosure provisions of § 1.56 and the information disclosure statement provisions of §§ 1.97 and 1.98 did not eliminate, or decline to adopt as final, provisions similar to the provisions of § 1.265(a).

Comment 249: One comment argued that the requirement for an examination support document was contrary to case law (citing In re Wilder, 736 F.2d 1516, 222 U.S.P.Q. 369 (Fed. Cir. 1984)) that

applicant is not under a duty to search.

Response: Initially, it is noted that Wilder does not stand for the proposition that applicant does not have a duty to search. Wilder involved a reissue application. That case held that an attorney's statement that his error was a misunderstanding of the scope of the invention arose resulting from a lack of a prior art search was a sufficient explanation to satisfy the requirements of the reissue rule regarding how the error arose. There is some case law, however, that indicates that applicant does not have a duty to search. See Nordberg, Inc. v. Telesmith, Inc., 82 F.3d 394, 397, 38 U.S.P.Q.2d 1593, 1595–96 (Fed. Cir. 1996); FMC Corp. v. Hennessy Indus., Inc., 836 F.2d 521, 526 n.6, 5 U.S.P.Q.2d 1272, 1275-76 n.6 (Fed. Cir. 1987); FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415, 5 U.S.P.Q.2d 1112, 1115 (Fed. Cir. 1987); Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1362, 220 U.S.P.Q. 763, 772 (Fed. Cir. 1984), cert. denied, 469 U.S. 821, 224 U.S.P.Q. 520 (1984). In view of these cases, the Office has stated that "faln applicant has no duty to conduct a prior art search as a prerequisite to filing an application for patent." See MPEP § 410. The case law, however, only discusses applicant's responsibility under the rules in 37 CFR

Part 1 that were in effect at the time that was relevant to these particular cases. The case law does not stand for the proposition that the Office cannot change the rules in 37 CFR Part 1 to require a preexamination search, either generally or, when an applicant presents more than five independent claims or more than twenty-five total claims in an application. Indeed, commentators have suggested that, especially after Festo X, a practitioner who declines to conduct any pre-filing search as a matter of practice may be falling short of the responsibility under 37 CFR part 10 to perform services with competence. See Schneck, The Duty to Search, 87

J.P.T.O.S. 689, 696-701 (2005).

Comment 250: One comment argued that an examination support document is not properly compared to an appeal is not properly compared to an appear brief since, in an appeal brief, the focus is on the examiner's rejection and interpretation of the references, whereas in an examination support document, applicant is required to provide a search, interpret claims, and identify all issues related to the search results with respect to each element of each claim.

Response: The Office did not compare an examination support document to an appeal brief. The Office simply indicated that the proposed "representative claim" examination approach was similar to the BPAI's representative claim practice. Nevertheless, the Office is not adopting the "representative claims" examination approach in this final rule.

Comment 251: One comment argued that the rule changes, especially the requirement for an examination support document, are not rationally related to achieving the stated goals of improving

patent quality and increasing efficiency.

Response: The Office is requiring an examination support document in those cases where applicants feel they need to have more than five independent claims or more than twenty-five total claims because these applications are the most burdensome for the Office. An examination support document will help the Office improve quality and increase efficiency because it will assist the examiner with the examination of the application. It should provide the examiner with the most pertinent prior art and an analysis of that art. Therefore, the changes being adopted in this final rule are related to the goals of improving quality and increasing efficiency.

Comment 252: One comment argued

that the examination support document requirement will increase demand for public searchers and this may drain the examining pool and worsen retention.

Response: It is the Office's experience that only a small number of examiners

who leave the Office do so to become public searchers.

Comment 253: One comment argued that practitioners do not draft patent applications to claim subject matter that they believe is not supported by the specification and thus it should be sufficient to merely assert that the claims are supported by the "entire provisions".

specification."

Response: The purpose of the requirement for a showing of where each limitation of the claims finds support under 35 U.S.C. 112, ¶1, is to assist the examiner in determining where the specification provides written description support for each claim limitation. An assertion by the practitioner that the claims are supported by the entire specification would not be of any assistance to the examiner.

Comment 254: Several comments argued that an examination support document should not be required until after the time for issuing a restriction requirement has passed because it is unfair to require applicant to prepare and file an examination support document when claims may be restricted such that fewer than ten representative claims are pending for examination. One comment suggested that a time period should be set in which the examiner must issue a restriction requirement or indicate that there will be none, and then the time period for submission of an examination support document should be set after that.

Response: As discussed previously, an applicant may submit a suggested restriction requirement accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims. See § 1.142(c) and the discussion of § 1.142(c). In this situation, an examination support document will not be required if the suggested restriction requirement is accepted. An examination support document will be required only if the suggested restriction requirement is not accepted, and the application contains more than five independent claims or more than twenty-five total claims, or more than five independent claims or more than twenty-five total claims to the elected invention and/or species if the examiner makes a restriction requirement that is different from the suggested restriction requirement.

Comment 255: One comment suggested that the Office should give assurances that: Like an information disclosure statement, nothing in an examination support document is an

admission of prior art; nothing in the examination support document would be considered as affecting the scope of the claims; and the examination support document would not be published and examiners would make no references to it in correspondence. One comment supported the use of a limited examination support document that would require applicants to identify where in the specification the corresponding structure, material or acts for functional claim elements may be found since this would improve examination efficiency and have minimal effects in litigation.

Response: Providing assurances that the examination support document would not affect the scope of the claims would not be appropriate. The showing of where each limitation of the claims finds support under 35 U.S.C. 112, ¶1, in the written description of the specification and the showing that includes the structure, material, or acts in the specification that correspond to each means-(or step-) plus-function claim element that invokes consideration under 35 U.S.C. 112, ¶6, may affect the interpretation of the claims. The determination on patentability is made on the entire record of the application. In order to provide a complete application file history, the examiner may find that it is necessary to state on the record any agreement or disagreement with applicant's explanation of how the claims are patentable over the references or applicant's explanation of where each limitation of the claims finds support under 35 U.S.C. 112, ¶ 1, in the written description. The application record is available to the publication under 35 publication of the application under 35 U.S.C. 122(b) and the issuance of a

patent on the application.

Comment 256: One comment suggested that the Office require applicants to provide claim charts that illustrate the differences between claims. The comment also suggested that applicants could be required to identify where support exists in the specification for the claims, or to identify groups of claims that are similar and define similar limitations.

Response: There is no prohibition against applicants submitting claim charts to illustrate the differences between claims. The Office does not consider it necessary at this time to make claim charts a requirement.

Comment 257: One comment inquired why, when claims in excess of ten are designated, a justification for all designated claims must be supplied and not just the number in excess of ten representative claims.

Response: The Office is not adopting the "representative claims" examination approach in this final rule. Under this final rule, applicant is required to file an examination support document when applicant presents more than five independent claims or more than twenty-five total claims in an application. In order to best assist in examination, the examination support document must cover all of the claims (in independent claims in excess of five or the total claims in excess of twenty-five.

I. The Office's Authority To Promulgate the Changes in This Final Rule

Comment 258: A number of comments argued that the changes to the rules of practice being adopted in this final rule are beyond the Office's rulemaking authority under 35 U.S.C. 2(b)[2). The comments argued that the proposed §§ 1.75(b), 1.78(d), and 1.78(f) are substantive and not procedural in nature because they affect an applicant's right to receive a patent for an invention or an applicant's ability to claim what the applicant regards as the invention.

the applicant regards as the invention.

Response: The Office has the authority under 35 U.S.C. 2(b)(2) to establish regulations, not inconsistent with law, which shall govern the conduct of proceedings in the Office. The "conduct of proceedings in the Office" provision of 35 U.S.C. 2(b)(2) (as well as former 35 U.S.C. 6(a)), however, is not limited to what might be characterized as "procedural" rather than "substantive" rules. See United States v. Haggar Apparel Co., 526 U.S. 380, 387–88 (1999). Simply contending that a regulation is "substantive and not procedural" fails to address the issue because a regulation that relates to application processing within the Office and that is not inconsistent with law falls within the Office's rulemaking authority. See In re Van Ornum, 686 F.2d 937, 945, 214 U.S.P.Q.2d 761, 768 (C.C.P.A. 1982) ("Appellants say the regulation is 'invalid on its face' but they do not explain why beyond contending it is 'substantive and not procedural.' We can give no weight to that contention. True, the rule is substantive in that it relates to a condition under which a patent will be granted which otherwise would have to be denied for double patenting. Much of the content of the PTO rules is 'substantive' in this respect. The regulation clearly relates to application processing within the PTO in a manner consistent with statutory and case law. which is its principal business."

The regulations at issue in this final rule concern application processing

exclusively within the Office. The changes to § 1.75 being adopted in this final rule govern the requirements relating to the examination of the claims in an application, as is provided for in 35 U.S.C. 131. The changes to § 1.78(d) being adopted in this final rule govern the conditions under which an application may contain or be amended to contain a claim under 35 U.S.C. 120. 121, or 365(c) to the benefit of a priorfiled application. The changes to § 1.78(f) being adopted in this final rule overn the requirements relating to the filing and examination of multiple applications by a common owner. The filing of an application for patent, amendment of an application, and the examination of an application are proceedings that take place exclusively within the Office. Therefore, regulations governing requirements relating to the filing, amendment, and examination of an application fall squarely within the Office's authority under 35 U.S.C 2(b)(2) to establish regulations which govern the conduct of proceedings in the Office.'

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The substantive right at issue during the patent examination process involves whether the applicant has met the conditions and requirements under title 35, United States Code, to be entitled to a patent, rather than the ability to file and maintain an unlimited number of continuing applications or requests for continued examination or the ability to refrain from obtaining and providing information pertinent to the examination of the application to the Office. See, e.g., 35 U.S.C. 101 ("[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"). The changes in this final rule do not preclude applicants from obtaining a patent on an invention, discourage, impede, or block an applicant's statutory right to a patent, or stifle inventors' rights to protect their inventions

The changes to continuing application practice adopted in this final rule do not set a per se limit on the number of continuing applications that an applicant may file. That is, applicant may automatically file a first and second continuation application without any justification and may file any number of additional continuation applications as long as he or she justifies each filing by a showing as to why the amendment, argument or evidence sought to be entered could not have been previously presented. Therefore, the changes to the final rule do not affect an applicant's

right to receive a patent for an invention. The modification to continuation practice simply improves the procedures under which an applicant may file a continuation application by focusing and consolidating the examination process. Furthermore, as an alternative, an applicant may choose to file an appeal when confronted with a rejection that he or she feels is improper. The changes adopted in this final rule to the continuing application practice prevent applicants from unnecessarily prolonging prosecution of applications before the Office.

The changes to the examination of claims practice adopted in this final rule do not prevent an applicant from presenting as many claims as are considered necessary or desirable to protect the full scope of the invention. The changes to the examination of claims practice adopted in this final rule simply provide that if an applicant exceeds or contemplates exceeding a specified threshold (five independent claims or twenty-five total claims), the applicant can provide for that eventuality by submitting additional information to the Office in an examination support document in order to facilitate effective examination of the application. The submission of an examination support document does not change the substantive criteria applied during examination (i.e., the statutory standards of patentability set forth in title 35, United States Code) to determine the applicant's entitlement to a patent.

The patentably indistinct claims

provisions do not affect applicant's patent rights because once the required explanation of patentable indistinctness has been provided, the claimed invention is examined on the merits and patentability is determined by the Office. The requirement that applicant show that claims are patentably distinct up front is simply a tool to focus and consolidate the examination of multiple

applications.

Comment 259: A number of comments suggested that a requirement of a showing to obtain an additional continuation application is contrary to 35 U.S.C. 120, 121, 365, 132(b), and other sections of title 35, United States Code, under which an applicant has a right to file an unlimited number of continuation applications. The comments suggested that: (1) The proposed rules disregard case law, in particular, In re Hogan, 559 F.2d 595, 194 U.S.P.Q. 527 (C.C.P.A. 1977), and In re Henriksen, 399 F.2d 253, 158 U.S.P.Q. 224 (C.C.P.A. 1968); (2) the Office does not have authority to limit

the number of continuing applications under 35 U.S.C. 2(b)(2) because the proposed rules are inconsistent with the law, and specifically do not "facilitate and expedite the processing of patent applications"; (3) the changes to § 1.78 cut off substantive rights for reasons other than patentability (as set forth in 35 U.S.C. 102, 103 and 112 of title 35. United States Code) and procedural misconduct, and thus are in violation of 35 U.S.C. 131; (4) the changes to § 1.78 are inconsistent with 35 U.S.C. 131 or 132, because the Director does not have the statutory discretion under these provisions to refuse to examine or to reexamine any application; (5) the requirement for a "showing" is contrary to law because the Office has no authority to deny an applicant the right to file a continuation application or a request for continued examination; (6) no justification or legal basis exists for the petition requirements set forth in the rules to get the benefit of an earlier filing date under 35 U.S.C. 120 or 365; (7) the Office has no statutory authority to delete a claim to priority in a continuing application filed according to the statutory provisions; and (8) applicants have a right to file a continuation application, as long as the reason is not improper, unduly successive or repetitive, citing Godfrey v. Eames, 68 U.S. (1 Wall.) 317, 325-26 (1864). Other comments, however, suggested that the proposed rules are consistent with both statute and case law given that: (1) The Office is not instituting a per se numerical limit on the number of continuation applications that an applicant may file; and (2) applicants are afforded an opportunity to justify by a showing the need to file additional continuation applications.

Response: None of the statutory provisions or case law cited by the comments provides that an applicant may file an unlimited number of continuing applications or requests for continued examination.

None of the statutory provisions related to continuing applications cited by the comment provide that an applicant may file an unlimited number of continuing applications. 35 U.S.C. 120 simply provides that an applicant may claim the benefit of the filing date of a prior-filed application provided that certain conditions are satisfied. 35 U.S.C. 121 provides that if the Director requires that an application containing claims to two or more independent and distinct inventions be restricted to one of the inventions and a non-elected invention is made the subject of a divisional application, the applicant in the divisional application may claim the benefit of the filing date of prior-filed

application provided that the conditions specified in 35 U.S.C. 120 are satisfied. 35 U.S.C. 365[c] provides that an applicant in an international application designating the United States may claim the benefit of the filing date of a prior-filed national application or a prior-filed international application designating the United States, and that an applicant in a national application may claim the benefit of the filing date of a prior-filed international application designating the United States, again provided that the conditions specified in 35 U.S.C. 120 are satisfied

120 are setisfied.
Since 35 U.S.C. 120, 121 and 365(c) all hinge upon 35 U.S.C. 120, the response focuses on that provision. 35 U.S.C. 120 provides that:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this

35 U.S.C. 120 (2000).

35 U.S.C. 120 has been revised significantly since its codification as part of the 1952 Patent Act. 35 U.S.C. 120 as codified in the 1952 Patent Act provided that: "[a]n application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the Inited States by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed

application." 35 U.S.C. 120 (1952). 35 U.S.C. 120 was amended in 1975 to add or as provided by section 363 of this title" to provide for claims under 35 U.S.C. 120 to the benefit of an international application filed under the PCT (i.e., international applications filed under 35 U.S.C. 363). Pub. L. 94-131, section 9, 89 Stat. 685, 692 (1975). 35 U.S.C. 120 was amended again in 1984 to substitute "by an inventor or inventors named in the previously filed application" for "by the same inventor" for consistency with the changes to the inventorship provisions of 35 U.S.C 116. Public Law 98-622, section 104(b). 98 Stat. 3383, 3385 (1984). 35 U.S.C. 120 was finally amended in 1999 to give the Director greater authority with respect to setting forth the time period within which claims to the benefit of a priorfiled application must be submitted by adding:

No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

Public Law 106–113, 113 Stat. 1501, 1501A–563 through 1501A–564 (1999). Thus, 35 U.S.C. 120 has never contained any language either expressly or implicitly stating that an applicant may file an unlimited number of continuing applications.

Turning to the legislative history of the 1952 Patent Act, it does not mention whether an applicant may file an unlimited number of continuing applications. The Senate Report simply documents that "[s]ections 120 and 121 express in the statute certain matters which exist in the law today but which had not before been written into the statute, and in so doing make some minor changes in concepts involved." S. Rep. No. 1979, at 2400 (June 27, 1952). The House Report contains basically the same description for 35 U.S.C. 120. The testimony from hearings before a Subcommittee of the Committee on the Judiciary, House of Representatives, for the 82nd Congress, held on June 13, 14, and 15, 1951, contains the same description for 35 U.S.C. 120 and little else of substance. For example, P.J. Federico testified: "Sections 120 and 121 express in the statute certain things which exist in the law today that have not been written into the statute, and in

so doing make some changes in the concepts involved." Patent Law Codification and Revision, 82d Cong. 39 (June 13, 1951) (statement of P.J. Federico, Examiner-In-Chief, United States Patent Office). Additionally, as noted in the congressional record for the 1952 Patent Act, 35 U.S.C. 120 codified existing patent practice. 98 Cong. Rec. 7, 9323 (June 28, 1952 to July 7, 1952) (statements of Senators Saltonstall and McCarran). In particular, "[t]he provisions set out in section 120 giving the applicant the benefit of the date of an earlier application by him for the same invention constitute a restatement of the former practice which was not. however, spelled out in the former law." Charles L. Zinn, Commentary on New

Title 35, U.S. Code "Patents" 2515. Secondary sources providing information about 35 U.S.C. 120 also do not offer guidance with respect to whether an applicant may file an unlimited number of continuing applications. The 1952 Patent Act was drafted by: (1) P.J. Federico, Examiner-In-Chief of the Patent Office; (2) Giles S. Rich, then an attorney of some twenty years representing the National Council of Patent Law Associations: (3) Paul Rose, chairman of the laws and rules committee of the American Patent Law Association; and (4) Henry Ashton, a representative of the coordinating committee on revision and amendment of the patent laws of the National Council of Patent Law Associations. See generally, Giles S. Rich, Congressional Intent—Or, Who Wrote the Patent Act of 1952, Patent Procurement and Exploitation (BNA 1963), reprinted in Nonobviousness-The Ultimate Condition of Patentability (John F. Witherspoon ed., 1983) (hereinafter "Rich on Congressional Intent"). Following enactment, Federico gave a series of lectures to teach the patent bar about the new law. Federico's lectures were transcribed, consolidated, and reprinted for many years in title 35, United States Code Annotated. See 35 U.S.C.A. sections 1 to 110 (1954). The Federal Circuit has considered Federico's Commentary to be "an invaluable insight into the intentions of the drafters of the Act." Symbol I, 277
F.3d at 1366, 61 U.S.P.Q.2d at 1519.
Federico explained that 35 U.S.C. 120

Federico explained that 35 U.S.C. 120 was "not specified in the old statute but was developed by decisions of the courts beginning with a decision of the Supreme Court of 1864, Godfrey v. Eames." P.J. Federico, Commentary on the New Patent Act, 75 J. Pat. & Trademark Off. Soc'y 3, 192 (Mar. 1993) (hereinafter "Federico's Commentary"). After offering this opening statement, he then set forth the three requirements for

a continuation application required by 35 U.S.C. 120 and elaborated on the meaning of each of these three

requirements. Although Federico's Commentary did not expressly mention any limits or conditions on an applicant's ability to file a continuation, it also did not state that the drafters contemplated allowing an applicant to file an unlimited number of continuation applications. Thus, there is nothing which indicates that the drafters intended to permit an applicant to file an unlimited number of continuing applications. What is more, Federico described examples of situations where continuations were used before the codification of the 1952 Patent Act:

Continuing applications are utilized in a number of different situations; for example, in the case of a requirement to restrict an application to a single invention a second application might be filed for the invention excluded from the the [sic] first application as explained in connection with the next section of the law, or a second application might be filed for a separable invention even though no requirement was made. A continuing application with the disclosure the same as a first application might sometimes be filed for procedural reasons with the first application thereafter being abandoned. And a continuing application with added subject matter may filed when the inventor has additional details relating to the invention which he wishes to disclose in the application; in such cases the second application would be entitled to the date of the first application only as to the common subject matter.

Federico's Commentary, 5 J. Pat. & Trademark Soc'y at 194.

Federico's list, albeit not exhaustive, suggests that patent practitioners used continuing applications in more limited circumstances before the 1952 Patent Act than today. His first example focuses on the divisional-type situation where a continuing (divisional) application is pursued to protect a second invention as a result of a restriction in the initial application. His third example focuses on a continuation-in-part situation where a continuing application is filed to enable an applicant to add subject matter to the application. Only his second example contemplates anything like current continuation practice where a continuing application is filed to pursue protection for an invention disclosed in the initial application. Federico nevertheless explained that the first application to which the continuing application claims priority is abandoned after the continuation is filed.

Federico did not include the then-rare situation in which the first application issued as a patent and the continuing

application was filed to pursue further protection for the invention of the patent on the first application. At the time of the 1952 Patent Act the double patenting doctrine did not permit a patentee to obtain more than one patent on patentably indistinct subject matter. See e.g., Miller v. Eagle Mfg. Co., 151 U.S. 186, 199 (1894) (the "a patent" for an invention provision does not permit a patentee to obtain more than one patent on patentably indistinct subject matter). Even after the 1952 Patent Act, the double patenting provision of 35 U.S.C. 101 ("a patent" for an invention), like its predecessor, was interpreted as precluding a patentee from obtaining more than one patent on patentably indistinct subject matter. See, e.g., In re Ockert, 245 F.2d 467, 469, 114 U.S.P.Q. 330, 332 (C.C.P.A. 1957)). It was not until 1970 that the Court of Customs and Patent Appeals held that the double patenting provision of 35 U.S.C. 101 precluded only "same invention" double patenting (i.e., two patents containing claims to identical subject matter) and permitted the use of a terminal disclaimer to overcome double patenting unless the application and patent were claiming identical subject matter. See In re Vogel, 422 F.2d 438, 441, 164 U.S.P.Q. 617, 622 (C.C.P.A. 1970). Thus, applicants today frequently do not abandon the initial application, but instead prosecute the initial application in parallel with the continuation application. Because of the development of terminal disclaimer practice, the authors of the 1952 Patent Act would not have contemplated a continuing application system under which an applicant would file an unlimited number of continuing applications.

Moreover, both before and long after the 1952 Patent Act applicants did not file long strings of continuation applications as is often done today. Indeed, the Board of Patent Appeals (Board) in Henriksen attempted to identify cases involving a series of more than three patents from cases litigated in the courts and patents issued by the Office during the week of April 26, 1966. Ex parte Henriksen, 154 U.S.P.Q. 53, 58-59 (Pat. Off. Bd. App. 1966). The Board in Henriksen was unable to isolate a single case involving a priority chain longer than three applications, with one exception that the Board nevertheless dismissed because the case was quite old, dating to 1867, and because the factual record was developed under different law. Id. at 58, n.2 (referring to the case as "an antique curiosity"). Based on the Board's research, it appears that priority chains

having more than three family members were actually uncommon, if they existed at all, before the 1952 Patent Act. Thus, if anything, the drafters of the Act, seeking to codify existing practice, did not envision that an applicant would use the provisions of 35 U.S.C. 120 to file and maintain an unlimited number of continuing

applications.
Following the enactment of the 1952 Patent Act, case law has specifically addressed the imposition of limits or conditions on continuation practice in the two cases cited by the comments (Henriksen and Hogan). In Henriksen and Hogan, the Court of Customs and Patents Appeals (C.C.P.A.) overturned rulings by the Board denying an applicant's priority claim to earlierfiled applications. In Hogan, the Board sought-without prior warning-to limit the number of continuations by restricting the applicant from claiming priority where the continuation applications covered a pendency period of twenty-four years. In Henriksen, the Board took the position that 35 U.S.C. 120 imposed a per se limit on the number of permissible continuations.

The changes adopted in this final rule, however, do not set a limit on the applicant's ability to claim the benefit of prior-filed application regardless of the pendency period, nor do they set a per se limit on the number of continuing applications that an applicant may file. See Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 FR at 50, 1302 Off. Gaz. Pat. Office at 1320 ("No limit is placed on the number of continuing applications.") Applicant may automatically file a first and second continuation application and further extend examination by filing a request for continued examination. After these options are exhausted an applicant may also file any number of third and subsequent continuation applications as long as the applicant justifies each filing by a showing that amendment, argument, or evidence sought to be entered could not have been presented earlier. The Henriksen court objected to the approach taken by the Board in changing continuing application practice retroactively. The Henriksen court objected to the Board changing the interpretation of the provisions of 35 U.S.C. 120 and applying that interpretation to previously filed applications. The Henriksen court specifically stated that:

The action of the board is akin to a retroactive rule change which may have the effect of divesting applicants of valuable rights to which, but for the change in Patent Office position brought about by the board's decision, they were entitled. Nothing appears in the Patent Office Rules of Practice or the Manual of Patent Examining Procedure which sanction such a result.

Henriksen, at 399 F.2d at 261-62, 158 U.S.P.Q. at 231. In Henriksen and Hogan, the Office had not promulgated any rules, let alone given the public notice of, or an opportunity to respond to, the ad hoc limits imposed. By contrast, the Office here is pursuing prospective rule making, having given the public notice of the changes to § 1.78 and an opportunity to comment.

Although the Court of Customs and Patent Appeals in a "post script" mentioned congressional resolution to remedy the abuses associated with continuation applications in both Henriksen and Hogan, the court seemed more concerned with the openness of the process for effecting change. Henriksen, 399 F.2d at 262, 158 U.S.P.Q. at 231. Here, the Office is adopting the prospective and open process missing in Hogan and Henriksen. The Office has given the public the opportunity to participate in shaping the rules for continuing application practice, received hundreds of comments, and has modified the proposed rules in response to those

public comments. More recent case law demonstrates that an applicant does not have the right to file an endless stream of continuing applications. See Symbol I, supra, In re Bogese II, 303 F.3d 1362, 64 U.S.P.Q.2d 1448 (Fed. Cir. 2002), and Symbol Techs. v. Lemelson Medical, Educ. & Research Found., 277 F.3d 1361, 61 U.S.P.Q.2d 1515 (Fed. Cir. 2002) (Symbol II). Symbol II, Bogese II and Symbol I suggest that the Office has the authority to place reasonable restrictions and requirements on the filing of continuing applications, just as it can place reasonable restrictions and requirements on the prosecution of those applications. In addition, the court in Bogese II expressly rejected the view that its previous case law (e.g., Henriksen) stood for the broad proposition that 35 U.S.C. 120 gave applicants carte blanche to prosecute continuing applications in any desired manner. Rather, it held that, while the statute itself provided no limit on the number of applications that may be copending, "[n]owhere does [the prior case law] suggest or imply that the PTO must allow dilatory tactics or that the PTO lacks inherent power to prohibit unreasonable delay in prosecution. Bogese II, 303 F.3d at 1368 n.6, 64 U.Š.P.Q.2d at 1452 n.6.

By amending the procedures under which an applicant may file

continuation applications, the Office is seeking to encourage the prompt presentation of amendment, argument and evidence in patent prosecution. To do so, the Office has determined that it must, at some point, change the continuing application practice that has facilitated the past dilatory presentation of amendment, argument and evidence that could have been presented earlier. The changes adopted in this final rule allow an applicant the flexibility to choose between filing a continuing application and filing an appeal, but do not permit an applicant to persist indefinitely before the examiner rather than seek an appeal. Therefore, this final rule does not preclude an applicant from obtaining a patent on an invention when requirements of title 35, United States Code, are satisfied. As explained in the Continuing Applications Proposed Rule, the changes to § 1.78 will "make the exchange between examiners and applicants more efficient, get claims to issue faster, and improve the quality of issued patents." See Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 FR at 50, 1302 Off. Gaz. Pat. Office at 1320.

Like the statutory provisions for continuing applications, the statutory provision for requests for continued examination, namely, 35 U.S.C. 132(b), does not provide that an applicant may file an unlimited number of requests for continued examination. As discussed previously, the provisions of 35 U.S.C. 132(b) were added relatively recently by section 4403 of the AIPA. See Public Law 106–113, 113 Stat. 1501, 1501A—560 (1999). 35 U.S.C. 132(b) provides that:

The Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant. The Director may establish appropriate fees for such continued examination and shall provide a 50 percent reduction in such fees for small entities that qualify for reduced fees under section 41(h)(1) of this title.

35 U.S.C. 132(b) (2000). The Office first implemented the provisions of 35 U.S.C. 132(b) by a final rule in August of 2000 that was preceded by an interim rule in March of 2000. See Request for Continued Examination Practice and Changes to Provisional Application Practice, 65 FR 50092 (Aug. 16, 2000), 1238 Off. Gaz. Pat. Office 13 (Sept. 5, 2000) (final rule), Changes to Application Examination and Provisional Application Practice, 65 FR 14865 (Mar. 20, 2000), 1233 Off. Gaz.

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The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), and was incorporated and enacted into law as part of Public Law 106-113. The Conference Report for H.R. 3194, 106th Cong., 1st. Sess. (1999), which resulted in Public Law 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. See H.R. Conf. Rep. No. 106-497, at 37 and 1089-174 (1999). A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott. See 145 Cong. Rec. S14,708–26 (1999) (daily ed. Nov. 17, 1999). This section-by-section analysis of S. 1984 provides with respect to 35 U.S.C. 132(b) that:

Section 4403 amends section 132 of the Patent Act to permit an applicant to request that an examiner continue the examination of an application following a notice of "final" rejection by the examiner. New section 132(a) authorizes the Director to prescribe regulations for the continued examination of an application notwithstanding a final rejection. The Director may also establish appropriate fees for continued examination proceedings, and shall provide a 50% fee reduction for small entities which qualify for such treatment under section 41(h)(1) of the Patent Act.

145 Cong. Rec. S14,718.

35 U.S.C. 132(b) does not specify the conditions and requirements for continued examination under 35 U.S.C. 132(b), but rather authorizes the Director to "prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant," See 35 U.S.C. 132(b). There is nothing in 35 U.S.C. 132(b) that precludes the Office from promulgating regulations that provide for no more than a single request for continued examination under 35 U.S.C. 132(b), or precludes the Office from requiring that any request for continued examination under 35 U.S.C. 132(b) include a showing as to why the amendment, argument or evidence could not have

been previously presented.

Comment 260: A number of
comments expressed the opinion that
any limitation on continuations should
be done legislatively by congressional
action and not by the Office via rule
making. Some comments argued that the
Office is usurping the legislative role of
Congress by modifying continuation
practice via regulation, arguing Congress
by inaction tacitly endorses the current
practice, and that the Federal Circuit
has acknowledged that limiting
continuation practice is an issue best
left to Congress, citing Ricoh Co., Ltd. v.